REMARKS

Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (claims 22-23 and 30-31) drawn to an isolated polypeptide selected from SEQ ID NO:1-6, biologically active fragments and immunogenic fragments and a method of producing the polypeptide.

Group II (claims 24-29 and 33-34) drawn to an isolated polynucleotide selected from SEQ ID NO:7-12, naturally occurring polynucleotide sequences, complementary polynucleotides, and RNA equivalents.

Group III (claim 32) drawn to a purified antibody.

Group IV (claims 35-36) drawn to a method of detecting target polynucleotides comprising hybridization techniques.

Group V (claim 37) drawn to a method of detecting target polynucleotides comprising amplification techniques.

Group VI (claims 38-41) drawn to a microarray and a method of generating an expression pprofile.

Applicants hereby elect, with traverse, to prosecute Group I, which includes and is drawn to Claims 22-23 and 30-31. Applicants further elect the SEQ ID NO:6 relative to the examination of these claims, again with traverse.

Applicants traverse both the restriction requirement and the obligation to elect a single sequence for prosecution for at least the following reasons.

I. The unity of invention standard ***must*** be applied in national stage applications

Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides:

> ... [W]hen the Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111....

> In applying PCT Rule 13.2 to ... national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2....

Id at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

> Examiners are reminded that unity of invention (not restriction) practice is applicable ... in national stage (filed under 35 U.S.C. 371) applications.

Id at page 1800-149, column 1.

The present application, filed under 35 U.S.C. §371 is a national-stage application; the Examiner is therefore **required** to apply the unity of invention standard.

II. Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions of the MPEP strongly support a finding of unity of invention among all of the claims in the present case

A. Unity of Invention is accepted as between claims to polypeptide sequences and claims to the polylnucleotide sequences which encode them

Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT provides that unity of invention is accepted as between claims to polypeptide sequences and claims to polynucleotide sequences encoding those polypeptides. Those Examples are cited in MPEP section 1893.03(d) at page 1800-149, column 2 ("[n]ote also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions...")

Thus, in the present case, unity of invention exists at least as between claims drawn to polypeptide sequences SEQ ID NO:1-6 (*i.e.*, claims 22 -23 and 30-31) of Group I and as to claims drawn to polynucleotide sequences which encode those polypeptides, SEQ ID NOs:7-12, respectively (*i.e.*, claims 24-29 and 33-34) of Group II.

Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to claims 22-29, 30-31 and 33-34, relative to SEQ ID NOs:6 and 12 and examine those claims in a single application.

B. Unity of invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend

MPEP section 1850(A) and 1893.03(d), which recite the provisions of paragraph (c) of Part 1 (entitled "Instructions Concerning Unity of Invention") of Annex B (entitled "Unity of Invention") to the Administrative Instructions Under the PCT, provides:

> **(A) Independent and Dependent Claims.**
>
> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).
>
> (i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention....

See MPEP section 1850(A) at page 1800-61. See also MPEP Appendix AI at page 53.

In the present case, claims 38, 40 and 41 all of which depend from claim 33, are all directed to compositions of matter, *i.e.,* to products. All of these claims contain all of the features of the independent claim.

Thus, it is improper to restrict claims 38, 40 and 41 from claims 33-34, as the Examiner has done. Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to the composition of matter claims related to SEQ ID NOs:6 and 12, and that at least those claims be considered together in a single application.

III. Unity of invention exists as between all of Applicants' claims

MPEP 1850 provides:

> Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Id at page 800-61.

MPEP 1893.03(d) similarly provides:

> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

Id at page 1800-149.

In the present case, unity of invention exists among all of Applicants' claims. The claimed polypeptide sequences and the claimed polynucleotide sequences encoding them are corresponding technical features which are common to all of Applicants claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

A. The claimed polypeptide sequences, and the claimed polynucleotide sequences encoding those polypeptide sequences, are corresponding technical features that are common to all of Applicants' claims and that serve to technically interrelate them

Applicants' claims recite *inter alia* the polypeptides SEQ ID NO:1-6, and polynucleotides encoding those polypeptides, which sequences include the polynucleotide sequences SEQ ID NO:7-12. Applicants respectfully submit that the claimed polypeptide sequences SEQ ID NO:1-6, and the claimed polynucleotide sequences encoding them, are corresponding technical features, given that the former are encoded by the latter, and conversely, the latter encode the former.

Further, the claimed polypeptide and corresponding polynucleotide sequences are common to all of Applicant's claims, given that each claim refers to one or both either explicitly or implicitly, by virtue of depending from a claim which makes an explicit reference to the claimed sequences.

Moreover, the claimed polypeptide and corresponding polynucleotide sequences serve to technically interrelate all of Applicants' claims. Applicants' composition of matter claims (22-

29, 32-34, 38, and 40-41) are drawn to either the polypeptide and polynucleotide sequences themselves (claims 22 and 23, drawn to polypeptide sequences, and claims 24-26 and 33-34, drawn to polynucleotide sequences), to compositions of matter which comprise the sequences as one element (claims 27-29, drawn to a recombinant polynucleotide comprising a promoter sequence and the polynucleotide, transformed cells, andd a transgenic organism comprising the recombinant polynucleotide, respectively, and claims 38 and 40-41, in which the polynucleotide is an array element), or to compositions of matter wherein the claimed sequences functionally limit the claimed subject matter (claim 32, drawn to an antibody which specifically binds a polypeptide of claim 22).

In Applicants' method claims (claims 30-31, 35-37, and 39), the claimed sequences serve as either the product of the claimed method (claim 30-31, drawn to a method of polypeptide production) and/or as a reagent for performing the method (claims 35-37, drawn to a method of detection of the polynucleotide, and claim 39 drawn to a method of generating an expression profile using the claimed polynucleotides as elements in an array).

Therefore, the claimed polypeptide and polynucleotide sequences are corresponding technical features which are common to all of Applicants' claims, and which serve to technically interrelate them.

In summary, the claimed polypeptide sequences and the claimed polynucleotide sequences which encode them are corresponding technical features which are common to all of Applicants claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept with respect to SEQ ID NOs:6 and 12, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application. Withdrawal of the restriction requirement and examination of all claims with respect to SEQ ID NOs:6 and 12 in the present case is therefore respectfully requested.

Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

CONCLUSION

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

Respectfully submitted,

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